DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
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# Statement of

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## Before the

## Subcommittee on Criminal Justice, Drug Policy, and Human Resources
## Committee on Government Reform
## House of Representatives

## "Hearing on Counterfeit Drugs within the United States"

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## INTRODUCTION

Mr. Chairman and Members of the Subcommittee, I am Randall W. Lutter, Ph.D., Acting Associate Commissioner for Policy and Planning, at the U.S. Food and Drug Administration (FDA or the Agency).

Thank you for the opportunity to testify about FDA's efforts regarding counterfeit prescription drugs. Let me emphasize that the overall quality of drug products that consumers purchase from United States pharmacies remains high. The American public can be confident that these medications are safe and effective. FDA cannot, however, offer the same assurance to the public about the safety and quality of drugs purchased from sources that are outside the U.S. regulatory system. My testimony today will focus on FDA's efforts to further secure the safety of our nation's drug supply.

## THE COUNTERFEIT DRUG PROBLEM

U.S. law defines counterfeit drugs as those sold under a product name without proper authorization, where the identity of the source of the drug is knowingly and intentionally mislabeled in a way that suggests that it is the authentic approved product. This definition can apply to brand name, generic products, or the bulk ingredients used to make the product. Counterfeit drugs under this definition may include products without the active ingredient, with an insufficient quantity of the active ingredient, with the wrong active ingredient, or with packaging that falsely suggests the drug was manufactured by the FDA-approved manufacturer. This definition depicts fraud toward the consumer believing they are receiving the genuine FDA-approved product and does not include products that are marketed as being similar to or a foreign version of an approved drug. Those types of products are illegal and referred to as "unapproved new drugs," not counterfeit.

Counterfeit prescription drugs are illegal and unsafe. Many are visually indistinguishable from authentic drugs, and they pose a potentially serious health threat.

FDA is concerned that the drug supply is under unprecedented attack from a variety of increasingly sophisticated threats. This disturbing trend is evident in the increased efforts to introduce counterfeit drugs into the U.S. market.

Although FDA believes domestic counterfeiting is not widespread, the Agency has witnessed an increase in counterfeiting activities and a more sophisticated ability to introduce finished dosage counterfeits into legitimate drug distribution channels. Illicit wholesale drug diverters provide the window through which most counterfeit drugs have historically entered legitimate distribution channels.

In fiscal year (FY) 2004, FDA's Office of Criminal Investigations (OCI) initiated 58 counterfeit drug cases, a significant increase from the 30 cases initiated in FY 2003. We believe that this is in part due to an increased awareness and vigilance at all levels of the drug distribution chain as a result of FDA's Counterfeit Task Force's, February 18, 2004, final report entitled, "Combating Counterfeit Drugs: A Report of the Food and Drug Administration." In addition, this increase

in investigations is due to increased referrals from and coordination with other state and Federal law-enforcement agencies and communication with drug manufacturers.

Fortunately, most of the counterfeit drugs at issue did not reach consumers because we focused our resources and developed proactive investigations that enabled us to identify components of counterfeit products and interdict finished counterfeit drug products before they entered domestic distribution. Counterfeit, stolen, and otherwise fraudulently obtained pharmaceutical drugs all enter legitimate channels through pre-existing illicit diversion networks. OCI enforcement efforts targeting these diverters also have resulted in detection and dismantling of counterfeit schemes. Without the intimate knowledge of diversion borne of extensive investigative experience it would be difficult, if not impossible, to effectively combat pharmaceutical counterfeiting.

Although the number of counterfeit drug cases has increased and the threat to the public health is real, most of the suspect counterfeits that we discovered in FY 2004 were found in smaller quantities, compared to those found in FY 2003.

Counterfeit drugs may be contaminated or contain inactive ingredients, incorrect ingredients, improper dosages, sub-potent or super-potent ingredients. As a result, patients may be at risk for serious adverse health consequences. For example, Procrit, an injectable, sterile drug used by cancer and AIDS patients, was counterfeited when the drug was replaced with non-sterile tap water, which could have caused a severe infection of the bloodstream.

In another counterfeiting incident, counterfeiters labeled aspirin tablets as Zyprexa, a drug for schizophrenia and bipolar disorder. This could have been particularly dangerous for patients who are aspirin-sensitive or aspirin-allergic, or who have bleeding disorders. In addition, patients who took the counterfeit drugs no longer received appropriate treatment for their illness.

Counterfeiters also have been known to use lower-strength active ingredients in their products. As a result, patients receive lower than expected doses of drug, leading to ineffective treatment and therapeutic failure.

While the rate of counterfeiting in the U.S. is difficult to estimate, on a global scale, counterfeiting is a widespread problem and affects both developing and developed countries. The World Health Organization (WHO) has reported that up to 25 percent of medicines consumed in poor countries are counterfeit or substandard. It has been reported that up to 50 percent of drugs for sale in some countries are counterfeit. Counterfeit drugs are most prevalent in developing countries.

This problem is not confined to counterfeiting the drug itself. Today, everything from product packaging to labeling and containers can be readily purchased, created or counterfeited, and counterfeiters and diverters take advantage of this opportunity. Moreover, the skill and ingenuity demonstrated by counterfeiters and diverters have improved significantly. As a result, more than ever before, well-organized criminals have the ability to exploit our regulatory system and profit at the expense of public health.

## PRESCRIPTION DRUG MARKETING ACT

Sixty-five years ago, Congress responded to widespread concerns about domestic drugs by enacting laws to provide FDA with the authority to create a system to assure the safety of the nation's drug supply.

During the 1980s, at least two high profile cases prompted further congressional action. In one instance, over two million unapproved and potentially unsafe and ineffective Ovulen-21 birth control tablets from Panama were distributed throughout the U.S. They were falsely imported as American goods returned. In another case, a counterfeit version of Ceclor, a widely used antibiotic at the time, entered into the U.S. drug distribution system from a foreign source. These concerns prompted Congress to pass legislation to correct this threat. After investigating the cases, Congress determined that the safeguards in the prescription drug distribution system were insufficient to prevent the introduction and retail sale of substandard, ineffective, or counterfeit drugs. Further, Congress found that a wholesale drug diversion sub-market had developed that prevented effective control over, or even routine knowledge of, the true sources of drugs.

Thus, in 1987, the Prescription Drug Marketing Act (PDMA) was enacted to further ensure the safety and effectiveness of prescription drug products and to safeguard the American public from the risk of counterfeit, adulterated, misbranded, sub-potent, or expired drugs. Key provisions of the PDMA include:

- A requirement for state licensure of wholesale distributors of prescription drugs.
- A requirement that wholesale distributors of prescription drugs who are not authorized distributors provide a statement of origin, also known as a drug "pedigree," to each wholesale customer. The pedigree traces each prior sale, trade, or purchase of the prescription drug.
- Requirements regarding the distribution and accountability of drug samples.

In 1999, FDA published final regulations implementing the PDMA. Shortly thereafter, the Agency received comments objecting to provisions concerning the pedigree requirement. These comments included letters and petitions and other communications from industry, industry trade associations, and Members of Congress. In addition, FDA received a petition requesting that the Agency issue a stay to suspend the implementation of the section of the final rule requiring: 1) a written agreement with a manufacturer establishing that a drug wholesaler was an authorized distributor, and 2) that unauthorized distributors provide a pedigree showing all prior drug sales extending back to the manufacturer. FDA received a second petition from the Small Business Administration raising these concerns and asserting that the rule would have severe economic consequences on more than 4,000 small businesses.

In response to these concerns, FDA delayed the effective date of certain regulations relating to written authorization agreements and drug pedigrees until October 1, 2001. We took this action to give the Agency time to evaluate the possible consequences of implementing these regulations

and to further evaluate the issues at stake. These concerns included the high cost and logistics of maintaining a pedigree and the inability, in some cases, to obtain a transaction history from prior authorized distributors traceable back to the manufacturer**,** thus calling into question the usefulness of the pedigree**.** FDA was told that taking steps to address these regulations, using traditional methods, could impose substantial cost at a time when access to affordable drugs is a major concern.

In June 2001, FDA submitted a Report to Congress required by the FDA Appropriations Act for 2001. Our report noted that in order for secondary wholesalers to comply fully with the pedigree requirements, Congress would have to amend section 503(e) of the Food, Drug, and Cosmetic (FD&C) Act to make the pedigree requirement universal, thus enabling so-called secondary wholesalers to obtain the transaction history from all prior purchasers of the drug, including those currently designated as authorized distributors. To allow Congress to consider the information contained in the Agency's report, and in light of the problems associated with written authorization agreements and drug pedigrees, in 2001, 2002 and 2003, FDA has annually delayed the effective date of these provisions of the PDMA rule.

In February 2004, concurrent with the release of FDA's Counterfeit Drug Task Force Report, FDA further extended the stay of these provisions until December 2006. As further discussed later in this testimony, FDA was encouraged by the comments and information that it received from drug supply chain stakeholders that an electronic track and trace system would be in place in the supply chain by that date. This electronic system would create a *de facto* pedigree that followed the product from the place of manufacturer through the U.S. drug supply chain to the final dispenser. If developed properly, this electronic pedigree could be used to meet the statutory requirements of the PDMA to provide a pedigree under certain circumstances. To allow stakeholders to continue to move toward implementing widespread use of an electronic pedigree and focus their efforts, the effective date of the relevant provisions were delayed until December 2006, a date that stakeholders believe was adequate to achieve the goals.

## COUNTERFEIT DRUG TASK FORCE

In order to explore all options to reduce drug counterfeiting, on July 16, 2003, the Agency established an internal FDA Counterfeit Drug Task Force as part of the heightened battle against the growing threat of counterfeit drugs. The Task Force was charged with developing recommendations for FDA, other government agencies, and the private sector to minimize the risks to the public from counterfeit drugs entering into the U.S. drug distribution system. The goal of this initiative is to enhance existing safeguards that protect the nation's drug supply from counterfeit drugs.

As part of this effort, the Task Force met with several Federal agencies, such as the Secret Service, U.S. Customs and Border Protection, the Bureau of Engraving and Printing, and the Department of Justice, as well as various private sector stakeholders. The Task Force also reviewed reports prepared by, or on behalf of, Federal and state governments, and heard from the public, including such stakeholders as pharmaceutical manufacturers, wholesale distributors,

pharmacy associations, consumer groups, academicians, independent consultants, and manufacturers of anti-counterfeiting measures.

FDA released the Task Force's final report on February 18, 2004, entitled, "Combating Counterfeit Drugs: A Report of the Food and Drug Administration." This report and a May 2005 update can be found on FDA's website at: *www.fda.gov/counterfeit.*

The comprehensive report highlights several measures that can be taken to better protect Americans from counterfeit drugs. These measures rely on public and private sector efforts to address six critical areas:

- Securing the actual drug product and its packaging;
- Securing the movement of the product as it travels through the U.S. drug distribution chain;
- Enhancing regulatory oversight and enforcement;
- Increasing penalties for counterfeiters;
- Heightening vigilance and awareness of counterfeit drugs; and
- Increasing international collaboration.

Technology: Securing the product, packaging, and movement through the supply chain

In the Report, we stated that it is critical to implement new technologies to better protect our drug supply. We concluded that a combination of rapidly improving track and trace technologies and product authentication technologies could be used to provide a greater level of security for drug products. These technologies are intended to secure the product, packaging, and movement of the product as it travels through the drug supply chain.

*Track and Trace Technology*

In the Report, we stated that adoption and widespread use of reliable track and trace technology may be feasible by 2007. This would help secure the integrity of the supply chain by providing an accurate drug "pedigree"; a record documenting that the drug was manufactured and distributed under secure conditions. We explained that the implementation of electronic track and trace mechanisms would provide better protection and we noted that radio-frequency identification (RFID) is the most promising technology to meet this need. RFID technology uses a tiny radio frequency chip containing essential data in the form of an electronic product code (EPC). Implementation of RFID will allow supply chain stakeholders to track the chain of custody (or pedigree) of every package of medication. By tying each discrete product unit to a unique electronic serial number, a product can be tracked electronically through every step of the supply chain.

Over the last year, stakeholders have made tremendous progress in the development and implementation of EPC/RFID. This is a huge endeavor that requires close collaboration among

all constituents of the pharmaceutical distribution system. We have observed and supported this collaboration, and we continue to support it today.

A critical piece of this undertaking is the development of standards for the type of technology to be used and the systems for storing and sharing pedigree information. This activity will ensure that the electronic track and trace technologies adopted are comprehensible and data communication systems are interoperable. We have been present at and actively participated in many industry, standard-setting, and government meetings and workshops where implementation issues were discussed.

We received a number of questions over the past year regarding RFID and regulatory issues from members of the supply chain. In response to these common questions, on November 15, 2004, we issued a Compliance Policy Guide for implementing RFID feasibility studies and pilot programs as an important and essential step in moving this technology forward. The Compliance Policy Guide presents FDA's current thinking regarding several labeling, current good manufacturing practices, and other regulatory issues that may arise by affixing an RFID tag to a drug product for a feasibility study or pilot program. Several members of the supply chain simultaneously announced their intention to move forward with pilot programs (joint programs across the supply chain or within an individual company) that will involve the tagging of products susceptible to counterfeiting. In fact, three major pharmaceutical companies said that they will incorporate an RFID tag into at least one of their products by the end of 2005. We have been in close communication with participants in these and other pilot studies and provided input when appropriate.
In November of last year, we also announced the creation of an internal, cross-agency "RFID Workgroup." This group is charged to monitor adoption of RFID in the pharmaceutical supply chain, pro-actively identify regulatory issues raised by the use of this new technology, and develop straightforward processes for handling those issues. We believe that the workgroup will improve communication with members of the supply chain on RFID related issues and will facilitate both the performance of pilot studies and the collection of data needed to formulate policy.

It is important to gain a better understanding of the effects of RFID on drug products, particularly biological products because they may be more susceptible to change in their environment. We developed a protocol for companies to follow for studies examining the impact of radio-frequency on drug and biological products. Also, a laboratory within FDA's Center for Devices and Radiological Health is conducting analyses of the heating and the radio-frequency field strengths induced in certain liquid pharmaceuticals by some RFID systems. To date, we have not received much data looking at the effects on drug and biological products and are looking at several options for how to obtain this information.

FDA continues to play an active role in supporting public and private sector efforts toward developing an "electronic safety net" for our drug supply, including the adoption and widespread use of reliable track and trace technology by 2007. We continue to facilitate and monitor standard-setting activities, including efforts by epcGlobal (an entity that has taken a lead role in developing standards) to establish standards for numbering systems, chip frequency, electronic

pedigree, and data-sharing and security. In addition, we continue to encourage and foster research on the use and potential impact of RFID on drug and biological products.

*Authentication Technology*
In the Report, we noted that authentication technologies for pharmaceuticals (such as color-shifting inks, holograms, taggants, or chemical markers imbedded in a drug or its label) have been sufficiently perfected that they can now serve as a critical component of a layered approach to control counterfeit drugs. FDA's Report acknowledged the importance of using one or more authentication technologies for drug products, in particular those most likely to be counterfeited. Over the past year, we have worked with individual drug manufacturers who sought to incorporate such technologies into their product, labeling, or packaging. When asked, we have provided advice and suggestions regarding application and use of authentication technologies and worked with sponsors on the regulatory issues associated with making changes to approved product labeling.

In the Report, we said that in order to facilitate the use of authentication technologies on or in approved products, we would consider publishing a draft guidance document on notification procedures for making changes to products, their packaging, or their labeling. We decided not to issue guidance in the past year because we would like to gain additional experience working with companies in their application and use of authentication technologies so the guidance can have appropriate general applicability.

We continue to work with companies and organizations to facilitate use of authentication technologies in products, labeling, and packaging.

<u>Regulatory Oversight and Enforcement</u>
*Electronic Pedigree*
In the Report, we said that adoption of electronic track and trace technology would help stakeholders meet and surpass the goals of the PDMA. We said that we intend to focus our efforts on facilitating industry adoption of this technology.

We are pleased with the progress stakeholders, standard-setting bodies, and software and hardware companies have made thus far toward implementing an electronic pedigree for drug products. We recognize that there have been, and continue to be, challenges along the way. Although we are optimistic that this progress will continue, and that widespread track and trace technology may be feasible by 2007, we are concerned that the private sector may not meet this and related goals stated in the Report.

We are closely monitoring the progress of widespread use of electronic pedigrees as we assess whether to lift, maintain, or pursue other options regarding the stay of implementation of the provisions in the PDMA final rule.

*State Efforts*
In the Report, we recognized the important role that the states have in regulating the drug supply chain, and we stated that adoption and enforcement of strong, proven anti-counterfeiting laws and regulations by the states would help in our collective effort to detect and deter counterfeit

drugs. FDA strongly supported the efforts taken by the National Association of Boards of Pharmacy (NABP) in revising the Model Rules for Licensure of Wholesale Distributors for states to adopt. These Model Rules make it difficult for illegitimate wholesalers to become licensed and then to transact business. Eleven states have laws in place that are similar to the Model Rules. FDA has provided advice and input on a few state legislative proposals and we recommend that more states move in this direction in the coming year.

NABP last year also announced the creation the Verified-Accredited Wholesale Distributors™ (VAWD) program as a complement to the Model Rules. Applicants for VAWD accreditation undergo a criteria compliance review, licensure verification, an inspection, background checks, and screening through NABP's clearinghouse. It is intended to provide assurance that the wholesale distribution facility operates legitimately, is validly licensed in good standing, and is employing security and best practices for safely distributing prescription drugs from manufacturers to pharmacies and other institutions. Indiana was the first state to pass a law that requires VAWD accreditation for all drug wholesale distributors who do business in Indiana.

In the Report, we said that there would be great value in the creation of a national list of drugs most likely to be counterfeited based on factors that are likely to contribute to counterfeiting risk. The Model Rules called for such a national list as a starting point for application of pedigree requirements in the short term so that there would not be 50 different state lists. In December 2004, NABP convened a National Drug Advisory Coalition, which included industry and state and national government representation. FDA has served in an *ex-officio* role on this Coalition. The Coalition developed criteria for inclusion or removal from such a list and created a national list that includes 31 drugs. FDA applauds NABP on this accomplishment.

We recognize that states have implemented and are considering provisions requiring a pedigree (in some cases electronic) for drug products. We are pleased that these efforts complement Federal requirements and believe that rapid and uniform implementation of a pedigree that starts at the point of manufacture and accompanies the drug product until it is dispensed would be beneficial. As stated in the Report, adoption and enforcement of the Model Rules by all states would have the greatest impact on protecting the nation's drug supply.

In the Report, we also said that increased penalties would help deter counterfeiting and more adequately punish those convicted. As we continue the efforts on the Federal level, it is equally important that states adopt stronger penalties (like those outlined in the Model Rules) so the penalties associated with counterfeiting drugs are commensurate to the significant threat they pose to the public health.

*Secure Business Practices*

In the Report, we described the important role that all participants in the drug supply chain have in adopting secure business practices. Around the time the Report was issued several trade associations for wholesale distributors issued guidelines for their members regarding best practices for drug distribution system integrity. In fact, in the past year, the Healthcare Distribution Management Association released new membership rules that require active members to adopt best practices that include extensive regulatory, financial, security, and due diligence processes and procedures.

It also is important to note that many of the secure business practices outlined in these trade associations' best practices guidelines are included in the Model Rules for Licensure of Wholesale Distributors for adoption by the states.

Increasing Penalties for Counterfeiters

FDA has contemplated this issue and contacted the Sentencing Commission to ask for higher penalties for counterfeiters. Although this is a complicated legal issue, we believe that more stringent sentencing guidelines would offer more appropriate penalties for offenses related to counterfeiting.

Heightened Vigilance and Awareness

*Health Professional Reporting Via MedWatch*

In the Report, we indicated that we would encourage and educate health professionals to use the MedWatch form as a mechanism to report suspect counterfeit drugs to FDA. To make the reporting of suspect counterfeits easier, we changed the instructions for the MedWatch reporting form, both paper and electronic versions, so reporters will know how and when to report suspect counterfeits. We also have amended the MedWatch website description of product problems and added "suspect counterfeit" to the list of product problems to report to FDA using the MedWatch form. FDA staff has promoted the use of MedWatch for reporting suspect counterfeits in numerous speeches to health professional organizations over the past year. A small number of such reports are starting to come in using the MedWatch form.

*Counterfeit Alert Network*

In the Report, we stated that we would create a Counterfeit Alert Network (CAN) and partner with health professional and consumer groups to provide timely and effective notification to their members or constituents of a verified counterfeit event. By signing the CAN co-sponsorship agreement, organizations become CAN partners and agree to deliver time-sensitive messages and information on specific counterfeit incidents and educational messages about counterfeits in general, as well as information about how and when to report suspect counterfeit drug products. In the past year, we formed the CAN and currently 13 organizations have signed the CAN co-sponsorship agreement.

Also, in the Report, we stated we would develop internal guidelines for the informational contents of outgoing FDA messages that would be useful to communicate a counterfeiting incident to CAN partners. In the past year, we have developed these guidelines, in the form of a template, in collaboration with CAN partners. This template will allow for the efficient preparation and delivery of uniform counterfeit alert messages for partners to further disseminate.

*Streamline FDA's Internal Rapid Response to Reports*

In the Report, we said that we would streamline our internal processes to respond quickly to reports of suspect counterfeits by improving coordination and communication among all initial responders in the Agency. In the past year we amended our internal standard operating procedures and developed a protocol for more efficient internal communication and coordination

when a suspect counterfeit drug is reported to the Agency, regardless of where the report is received (e.g., MedWatch, an FDA field office, call to the FDA hotline).

*Educating Consumers and Health Professionals*

In the Report, we noted that educating consumers about the risks of counterfeits is a critical piece of the effort to stop counterfeits from entering the stream of commerce. In the past year we have taken many steps towards educating consumers. First, we developed two public service announcements (PSAs) geared to consumers. These PSAs ran in 4.5 million magazines. In addition, 4.6 million medication leaflets distributed by retail pharmacies with patient's prescriptions also carried these PSAs along with additional consumer information about counterfeit drugs. Also, FDA drafted an article about counterfeit drugs that was printed in several local papers nationwide, with an estimated readership of about 9.5 million consumers.

We also set up a webpage on FDA's website for consumers to obtain information about counterfeit drugs, FDA initiatives, and educational information. This website can be found at *www.fda.gov/counterfeit*. In addition, the National Consumers League developed a highly informative website containing useful consumer information about counterfeit drugs.

In the past year, FDA partnered with the National Health Council (NHC) to jointly create and disseminate educational messages on counterfeit drugs. NHC is a private, non-profit organization of over 100 national health-related organizations. Under this partnership, messages to raise awareness of the dangers of counterfeit drugs and how to avoid them will be developed and tested to measure their effectiveness. In addition, products will be created to deliver these messages to the target audience.

In addition, FDA is developing educational messages to inform pharmacists about how to recognize counterfeits, counsel patients on how to minimize the risk of exposure to counterfeits, and on how to notify FDA if a counterfeit drug is suspected. These efforts are in the early stages.

In the Report, we said that we would re-launch our safe online buying practice campaign. In March 2005, we launched a new campaign with tips for consumers on how to buy drugs safely on the Internet and minimize their risks of getting a counterfeit or otherwise substandard drug.

In the coming months, we plan to take steps to increase dissemination of the PSAs and counterfeit drug messages. We also will continue to update and post relevant information on our counterfeit drug webpage. We also plan to continue to work with the NHC to finalize educational messages and develop a dissemination strategy for those messages. We are currently working with pharmacy organizations to finalize educational messages for pharmacists and develop a strategy to disseminate these messages.

<u>International Collaboration</u>

In the Report, we recognized that counterfeit drugs are a worldwide concern, and we stated that we would collaborate with foreign stakeholders to develop strategies to deter and detect counterfeits globally. In February 2004, the WHO hosted a meeting to discuss an approach for developing global strategies for combating counterfeit drugs. FDA participated in this meeting and supports WHO's efforts in this area. It was decided at the WHO meeting that a concept paper would be drafted with a proposed strategy to address this problem. In March 2005, we

attended the Fourth Pan American Conference on Drug Regulatory Harmonization held by the Pan-American Health Organization (PAHO) where a report was presented and recommendations were discussed regarding combating counterfeit drugs in the Americas. FDA's counterfeit drug initiative is consistent with the recommendations of the PAHO report.

OCI, within FDA, continues to work with foreign law-enforcement agencies directly and through Interpol on individual international counterfeit cases.

OCI also has provided training on counterfeit drugs to foreign law-enforcement, customs and judicial officers from various parts of the world through the U.S. Patent and Trademark Office, Intellectual Property Enforcement Academy. In addition, in the past year, several individual countries have sought FDA's insights, advice, and/or training on combating counterfeit drugs. Although the approaches that we outlined in the Report were specific to the U.S. drug distribution system, many of the principles outlined in the Report are applicable generally.

## RECENT SIGNIFICANT COUNTERFEIT CASES

Below are a number of significant counterfeit drug cases that were closed in the past year:

### Counterfeit Lipitor

Although we continue to see individuals dealing in counterfeit drugs via the Internet, there are others that use the under-regulated system of secondary wholesalers to distribute their counterfeit drugs, which then end up at the pharmacy level. The Albers Medical investigation is the most prolific example. On August 21, 2005, the U.S. Attorney's Office for the Western District of Missouri issued a press release announcing that three businesses and eleven individuals were indicted for their involvement in a $42 million dollar conspiracy to sell counterfeit, smuggled and misbranded Lipitor and other drugs and for participating in a conspiracy to sell stolen drugs. As part of this investigation, FDA initiated a recall of more than 18 million Lipitor tablets, which ranks as one of the largest recalls in the history of criminal investigations of counterfeit medications.

Participants in this scheme conspired to purchase and sell counterfeit, misbranded and illegally imported drugs. Foreign versions of Lipitor and Celebrex were smuggled into the U.S. from South America and re-sold after being re-packaged to conceal the true origin of the drugs. Counterfeit Lipitor also was manufactured in South America and then smuggled into the U.S. where it was co-mingled with the genuine foreign Lipitor and sold in the U.S. In addition, participants conspired to buy, sell and traffic almost eight million dollars worth of stolen Glaxo Smith Kline and Roche drugs, using fake pedigrees to launder the drugs and thereby concealing that they were stolen. There also were charges related to the sale of counterfeit Procrit, as well as counterfeit and misbranded Serostim and Neupogen. Procrit is an injectable drug used in the treatment of anemia and Neupogen is an injectable drug used by cancer patients to stimulate the production of white blood cells in order to decrease the incidence of infections.

### Counterfeit Lipitor and Viagra

In another counterfeit Lipitor case, an OCI undercover operation resulted in the arrest and conviction of a Belize citizen for violating Title 21, United States Code (U.S.C.) §331 (a) –

Introduction into Interstate Commerce of a Misbranded Drug. In September 2004, the defendant was sentenced to 10 months incarceration and 1 year probation.

**Counterfeit Viagra, Cialis, and Lipitor**
On September 12, 2005, the U.S. Attorney's Office for the Southern District of Texas announced the indictment and arrest of an individual from the state of Washington for his alleged involvement in the importation from China and subsequent distribution of counterfeit drugs, including Viagra and Cialis. This joint OCI and U.S. Immigration and Customs Enforcement (ICE) investigation was significant in that it also involved the direct assistance of OCI and ICE in China to determine the source of the counterfeits. As a result of this collaborative effort, Chinese authorities arrested 11 individuals who will be prosecuted by the Chinese government for their involvement in manufacturing and distributing counterfeit Viagra, Cialis, and Lipitor. In addition to the arrests, Chinese officials recovered 600,000 counterfeit Viagra labels and packaging, 440,000 counterfeit Viagra and Cialis tablets, and 260 kilograms of raw materials used to manufacture counterfeit drugs.

**Counterfeit Risperdal and Zyprexa**
In October of this year, the U.S. Attorney's Office for the Southern District of Florida issued press releases following the sentencing of two individuals involved in drug diversion and counterfeiting. One individual was sentenced to 30 months in jail for counterfeiting Zyprexa and Risperdal prescription labels and selling them to various individuals. In a related investigation, a second individual was sentenced to 24 months in jail for the illegal wholesale distribution of prescription drugs and possession with the intent to distribute controlled substances.

**Counterfeit Drugs from Mexican Border Pharmacies**
In the summer of 2004 and again in the spring of 2005, OCI received Voluntary Suspect Counterfeit Drug notifications from the drug manufacturers of Zocor, Carisoprodol, Lipitor, Viagra, and Evista. Counterfeit versions of these drugs were being sold to U.S. consumers from Mexican pharmacies along the U.S. border. The analysis of all these drugs showed they either contained little or no active ingredients.

OCI coordinated with FDA regulatory authorities who issued two *Talk Papers* (July 30, 2004, and May 10, 2005) alerting consumers to the counterfeit drugs. OCI and FDA regulatory authorities also established contact with the Mexican Federal Commission for Protection from Sanitary Risks to provide them with details and samples of the counterfeit drugs so they could take appropriate action in Mexico.

**Genapharm.com (Counterfeit Human Growth Hormone)**
On March 9, 2004, an Austin, Texas man pled guilty to four counts of conspiracy to introduce misbranded and unapproved new drugs into interstate commerce, counterfeiting human growth hormone, and possessing controlled drugs with intent to distribute. Two other persons involved in these offenses were previously convicted and sentenced.

**Counterfeit Viagra**
On June 23, 2004, an individual pled guilty to charges of conspiracy, trafficking in counterfeit goods, and a felony violation of the FD&C Act. In pleading guilty, the defendant admitted that he conspired with a manufacturer in Beijing to import thousands of counterfeit Viagra tablets into the U.S., which he would then resell. The defendant was sentenced, on March 25, 2005, to 18 months in prison, followed by 3 years probation and was fined $6000.

**Counterfeit Serostim**
On June 16, 2004, an indictment was unsealed in San Diego that charged an individual with conspiring to unlawfully distribute human growth hormone and trafficking in counterfeit goods. According to the indictment, this individual obtained counterfeit Serostim and sold it to bodybuilders who did not possess lawful prescriptions for the drug. Another individual involved in this investigation pled guilty to similar charges on February 19, 2003. Serostim is a prescription drug containing the active ingredient "somatropin," a form of human growth hormone. Serostim is approved by FDA for use in the U.S. to treat AIDS wasting disease.

**Counterfeit Labeled Pharmaceuticals**
An Alabama drug wholesaler was convicted for violating Title 21, U.S.C. §331 (i) (3) – Selling and Holding for Sale a Counterfeit Drug. In October 2004, the company was sentenced to 5-years probation and fined $24,000.

**Counterfeit Viagra**
In January of this year**,** a southern California man pled guilty to importing counterfeit Viagra from China and manufacturing 700,000 counterfeit Viagra tablets at a lab in the U.S. An accomplice was convicted of similar charges in September 2004. The total value of the counterfeit Viagra in this case is more than $5.65 million.

**World Express Rx**
In January of this year, a San Diego man was sentenced to serve a 51-month prison term and forfeit substantial cash proceeds for his role in operating a large Internet pharmacy scheme. The drugs distributed included a variety of products counterfeited in Mexico, smuggled into the U.S. and sent throughout the country. Some of the ingredients for the drugs were shipped from India and China. In other instances, unapproved and counterfeit drugs made in India and Pakistan entered the U.S. via the Bahamas. At least 14 other individuals also are being prosecuted in California or Florida as part of this international conspiracy.

## MONITORING THE TAMIFLU SUPPLY

As the threat of pandemic flu emerges as a public health threat, FDA anticipates an increase in the sale of counterfeit or fraudulent treatments. Presently, the Agency is not aware of any counterfeit Tamiflu cases in the U.S. However, through the implementation of the measures outlined in FDA's Counterfeit Drug Task Force Report and the vigilance of our experienced enforcement and investigative staff, efforts are in place to deter and detect counterfeiters and parties who sell fraudulent or phony products to treat or prevent Avian flu.

## CONCLUSION

Significant progress has been made towards implementing the measures outlined in FDA's Combating Counterfeit Drugs Report, issued in February 2004. Although the use of electronic track and trace technology is still in the implementation stage, adoption and widespread use is closer to becoming a reality as stakeholders work diligently to find solutions to the challenges faced along the way. The use of authentication technologies is gaining acceptance as manufacturers realize that steps should be taken to protect their products from sophisticated counterfeiters. States are starting to adopt stricter laws and harsher penalties to ensure that only legitimate wholesalers do business in their state and they are taking measures to do their part in protecting supply chain integrity. OCI will continue to target illicit diversion to further protect the integrity of the drug supply. Trading partners in the drug supply chain also are taking steps to ensure secure business practices are adopted and utilized as drug products are bought and sold. Educational efforts have been undertaken to help health professionals and consumers develop a greater awareness and knowledge about counterfeit drugs and how to minimize the risks of exposure. In addition, efforts are underway to tackle counterfeit drugs on a global level.

Despite the progress made, there remains a viable and concrete threat of counterfeit drugs entering the U.S. drug distribution system. We must all continue to work together to expeditiously pursue the measures outlined in the Report to further protect the safety and security of the U.S. drug supply.

I would like to thank the Subcommittee for this opportunity to testify today on this important issue. I would be pleased to respond to any questions.

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